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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,177	01/29/2001	Ake Lindahl	003300-696	2132

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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

FUBARA, BLESSING M

ART UNIT.	PAPER NUMBER
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1615

DATE MAILED: 01/25/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,177

Applicant(s)

AKE LINDAHL

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 and 10. 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment filed 11/13/00.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-3, 26-28, the term "such" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 17, the phrase "such as" in lines 4 and 9, renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "preferably" is indefinite and thus renders claims 6, 7, 23 and 25 indefinite.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

Art Unit: 1615

raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claims recite "preferably" and that term represents a range within a range.

4. Claims 1, 3, 13, 27 and 28 recite "and/or" which is indefinite, see *ex parte Andereg* 51 USPQ 66.

5. Parenthesis is generally not permitted in a claim (see claim 1 for "(s)" in line 9 and 14 and line 6 and line 8 or claims 2 and 3 respectively. Other examples of the use of parenthesis appear in claims 4-8, 12-16 and 26-28. These claims contain 9s), (have) and (are).

6. The phrase "to such chemical reaction" and "of such chemical" is unclear (see claims 1-3 and 26-28). The claims may recite...said chemical reaction... or ...the chemical reaction... if there is appropriate antecedence for the phrase or term.

7. The terminology "derivatives" is indefinite (see line 6 of claim 17). Saccharide derivatives encompass all known and yet to be discovered saccharide derivatives. Applicants have not claimed the saccharide derivatives that fall within the scope of the invention. There is no definition in the disclosure about the saccharide derivatives (lines 15 and 16 of page 12) that fall within the scope of the invention. There is no statement in the specification that says that saccharide derivatives are or by saccharide derivatives we mean....

Art Unit: 1615

8. Regarding claim 17, the term "type" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

9. The recitation of "higher" in claims 1-3, 17, 26 and 27 renders the claims indefinite because the meets and bounds of "higher" are not defined in the claims. How much is higher?

10. Claims 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. There are no clear method steps in these claims. Claims 26 and 27 read like composition claims instead of method claims.

11. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

12. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification including the claims.

Observation:

Claim 29 appears to depend from claim 18. There is no recitation from monomeric alcohol in claim 19.

Line 1, of claim 27, has "is" after composition. The "is" appears to be left inadvertently after the amendment.

13. Claim 29 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 20.

When two claims in an application are duplicates or else are so close in content that they both

Art Unit: 1615

cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Specification

14. The disclosure is objected to because of the following informalities: Page 24 of the disclosure has a figure. The figure should be deleted from that page and submitted as a drawing on a separate sheet of paper to comply with the requirements of 37 CFR 1.84 or 1.52. The description of the drawing must include a description of the new figure/drawing submitted in response to this action.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

Art Unit: 1615

122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 1-5, 8-14, 17, 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Farinas et al. (US 5,906,830).

Farinas discloses a method for preparing transdermal drug delivery systems containing supersaturated drug reservoirs (abstract). The drug is heated to a temperature just higher than the calculated depressed melting temperature (column 6, lines 12-21). Farinas discloses that an amount of drug molecule is dispersed in the reservoir material at a concentration that is greater than the solubility of the drug in the reservoir material at room temperature to give a supersaturated drug reservoir (column 5, lines 1-10). The components of the reservoir include polymeric materials selected from polysiloxanes, polyacrylates and polyurethane adhesives (column 6, line 61 to column 7 line 24). Drugs that may be incorporated in the drug delivery system are narcotic agonists and antagonists, serotonergic agonists, antihistamines, anti-inflammatory agents, benzodiazepines, dopaminergic agonists and antagonists, hormones and antipsychotic agents (column 7, lines 39-64). The drug formulation further includes carriers or vehicles selected from stabilizers, antioxidants, anti-irritants, cellulosic polymers, polyvinyl alcohol and polyacrylic acid. See also claims 1-14. The teachings of Farinas anticipate the claims.

17. Claims 1, 17-20, 23-24 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindahl (WO 97/00670).

Lindahl discloses a composition comprising a polyester matrix and biologically active agent, acyclovir (abstract, examples 2-6 and claims 1-31). The composition comprises a matrix,

Art Unit: 1615

a reaction product of citric acid and propylene glycol. The process for forming the composition is a simple mixing of citric acid, the propylene glycol and the biologically active agent, heating the mixture at an elevated temperature and then cooling down the resulting mixture (examples 2 and 3). The compositions also contain plasticizers (page 10, lines 5-30). Examples of biologically active agents of Lindahl are vitamins, antiviral agents, anti-inflammatory agents, anticancer agents, antimicrobial and antifungal agents (page 9, lines 2-15). Lindahl anticipates the claims.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 1-17 and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farinas et al. (US 5,906,830).

The teachings of Farinas are discussed above. The method of Farinas comprises mixing polymeric material and a drug formulation, removing the most of the solvent, evaluating the depressed melting temperature of the drug-polymer mixture, heating the mixture to a predetermined temperature and cooling the heated mixture to form the supersaturated reservoir (claim 1). The invention does not teach any particular method steps. However, the prior art is silent on the degree of saturation. Although, the invention recites "higher" degree of saturation, the invention does not indicate what "higher" would be in terms of saturation. Therefore, it

Art Unit: 1615

would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Farinas. One having ordinary skill in the art would have been motivated to prepare a supersaturated drug delivery reservoir according to the method of Farinas. Since applicants fail to specify what higher degree of saturation is, in the absence of evidence to the contrary, the supersaturated drug reservoir is as supersaturated as the drug formulation of the invention.

20. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindahl (WO 97/00670).

The teachings of Lindahl are described above. But Lindahl is silent on the saturation condition of the formulation. But saturating a matrix with a biologically active agent is a matter of degree. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Lindahl. One having ordinary skill in the art would have been motivated to prepare the composition of Lindahl. Lindahl's process of making the composition is similar to the mixing process of the invention (compare lines 24-30 of page 14). In the absence of unexpected result supersaturating a matrix with a biologically active agent is not critical over the prior art and not inventive over the prior art.

Double Patenting

21. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Art Unit: 1615

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of copending Application No. 09/700,176. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

24. Claims 1-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 09/700,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the invention recites that the saturation of the biologically active agent in the carrier matrix is higher than in the starting carrier, in the absence of indicating what the higher degree of saturation is, the invention is obvious over the supersaturated composition of the copending application.

Art Unit: 1615

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
January 16, 2002

THURMAN K. PAGE
SUPERVISOR
TECHNOLOGY CENTER 1000